

510(k) Summary according to 807.92(c)

JAN 18 2011

Date prepared: January 17, 2011
Contact: Jessee Hunt, President
4-Web Spine, Inc.
6629 Whispering Woods Ct.
Plano, TX 75024
972-841-6126

Trade Name: ALIF Spinal Truss System ® Interbody Fusion Device
Product Class: Class II
Classification: 21 CFR §888.3080 Orthosis, intervertebral fusion
Product Codes: MAX
Panel Code: 87

Indications for Use:

The ALIF Spinal Truss System (STS) Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Device Description:

The ALIF STS Interbody Fusion Device is a titanium implant that is designed to provide mechanical support to the lumbar spine while biologic fusion takes place. The device is an "open architecture" design consisting of trusses mathematically designed to provide maximum support with the greatest amount of open space throughout the implant for bone growth and fusion. The implant is made from Ti6Al4V alloy.

The device is available in three basic "footprint" sizes, small, medium and large. These sizes are available in zero degree lordosis and 8 degree lordosis and each of these in 8 heights ranging from 10mm to 17mm in 1mm increments.

Predicate Device(s):

The ALIF STS® Interbody Fusion Device was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. The predicate devices include the BAK Interbody Fusion Device (Spine-Tech, P950002), Infix System from Spinal Concepts (K031672) and the Brantigan Lumbar I/F Cage (AcroMed, P960025). (Add Titan Spine?)

Performance Testing:

Preclinical testing performed on the 4-Web STS® Interbody Fusion Device included static compression, static compression shear, static torsion, dynamic axial compression, and dynamic

compressive shear mechanical testing per ASTM F2077. Other mechanical tests included subsidence per ASTM F2267-04 and expulsion testing per an industry accepted methodology. Finite Element Analysis to assess mechanical stiffness, quantify stresses and intra-cage pressure and to quantify porosity was also completed. Finally, an animal study in sheep which demonstrated fusion was performed. The outcome of pre-clinical testing performed indicates that the ALIF STS® Interbody Fusion Device is substantially equivalent to the predicate devices..



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

4-Web Spine, Inc.
% Richard Jansen, Pharm.D.
Silver Pine Consulting
13540 Guild Avenue
Apple Valley, Minnesota 55124

JAN 18 2011

Re: K083894

Trade/Device Name: ALIF Spinal Truss System® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 22, 2010
Received: December 27, 2010

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'Mark N. Melkerson', with some additional scribbles below it.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K083894

Indications for Use:


The ALIF Spinal Truss Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083894